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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,658	01/24/2005	Hideki Murata	09859/0202424-US0	8728

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,658	MURATA ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 13, 2007, has been entered.

Claims 1-6 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 56-131394.

JP `394 discloses a method wherein 10 g of crude coenzyme Q_{10} (which is another term for ubiquinone-10, see abstract of Frei et al, PNAS, 1990, 87: 4879-4883) produced by fermentation of *Protaminobacter ruber* (a bacteria), was dissolved in a solution which was furthered treated with 20 ml of a 28% NH_4OH-MeOH (ammonium hydroxide-methanol) (5:95) mixture at 10°C for 20 minutes. See the CAPLUS English abstract. The crude coenzyme Q_{10} can be considered to be a processed product of a culture of ubiquinone-10-producing microorganism, or a partially purified product of ubiquinone-10. This step meets nearly all the requirements of step [1] of instant claim 1, except that it does not teach the volume of the methanol solution relative to the volume of product being treated as recited in instant claim 1. Next, after retaining the resulting mixture at 10°C for 20 minutes, the NH_4OH-MeOH layer is discarded, and this step meets the limitations of step [2] of instant claim 1. Then, the remaining impurities (insoluble matter) are extracted a second time with 20 mL of 95% MeOH solution at 10°C for 20 minutes. This step meets nearly all the limitations of step [3] of instant claim 1, except for the temperature at which the resulting mixture is retained. Next, a purified coenzyme Q_{10} is recovered from this extraction, thus insoluble matter had to have been removed, thus step [4] of instant claim 1 is taught by the reference. Finally, the purified coenzyme Q_{10} is crystallized from acetone.

As discussed above, the methods disclosed in JP `394 differ from the instant invention in that JP `394 does not teach the final concentration of 50 to 100 v/v% of methanol solution in the total volume of the resulting mixture, as recited in step [1] of instant claim 1. Nevertheless, the selection of a specific volumetric ratio of methanol solution to the total resulting mixture would have been a routine matter of optimization on the part of the artisan of ordinary skill in the art,

said artisan recognizing that the extraction of impurities would have been dependent on the concentration of the methanol solution present in preparing the resulting mixture. Thus, limitations recited in step [1] of instant claim 1 are rendered obvious by the reference.

Additionally, as discussed above, the methods disclosed in JP `394 differ from the instant invention in that JP `394 does not teach the temperature at which the resulting mixture is retained after the insoluble matter is treated with methanol solution, as recited in step [3] of instant claim 1. Nevertheless, the selection of specific suitable temperatures for retaining the resulting mixture, including that claimed, clearly would have been an obvious matter of optimization on the part of the artisan of ordinary skill in the art. Thus, all limitations of step [3] of instant claim 1 are rendered obvious by the reference.

Finally, it is noted that it would have been obvious to one skilled in the art to have repeated the extraction steps by adding methanol to the coenzyme Q-10-containing solution after removal of insoluble matter to achieve the predictable result of purifying coenzyme Q-10. The combination of methanol and coenzyme Q-10 is considered a "methanol solution containing ubiquinone-10," thus meeting the requirements of step [5] in instant claim 1.

Therefore, JP `394 renders obvious instant claims 1 and 3. Given that a crystallized pure coenzyme $Q_{10}$ is taught by JP `394 as the final product of their method, instant claim 5 is also rendered obvious. Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have repeatedly treated the insoluble matter with the 95% methanol solution following initial treatment of crude coenzyme Q_{10} with a methanol solution, therefore rendering claim 2 obvious. One of ordinary skill in the art would have been motivated to repeat this step in order to have further purified the insoluble matter by extracting

more of the impurities by performing extra extractions. Repetition of methanol treatment would have ensured maximal extraction and maximal removal of impurities. The repetition of process steps would have been prima facie obvious in the absence of new or unexpected results. Thus, claim 2 is rendered obvious by the reference.

Note that JP '394 indicates an 82% pure crystalline product. Through repeated methanol treatment, there would have been a reasonable expectation of success in obtaining a crystal of ubiquinone-10 having a purity of 90.0% or more given that repeated methanol treatment would have been expected to increase the removal of impurities. Thus, instant claim 6 is rendered obvious.

Also, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used any of the forms recited in claim 4 as the crude coenzyme Q_{10} required for the practice of JP '394. One of ordinary skill in the art would have been motivated to do this since there would have been a reasonable expectation of success in successfully purifying coenzyme Q_{10} with any of these forms. Moreover, one would have been motivated to have used these forms since these forms may be stored for long periods of time. Thus, claim 4 is rendered obvious by the reference.

Finally, it is noted that JP '394 does not expressly disclose adding a methanol solution to a partially purified product of ubiquinone-10 selected from the group consisting of ubiquinone-10-containing dried products, freeze dried products, and crystallized products. However, there would have been a reasonable expectation of success in successfully purifying ubiquinone-10 from a variety of ubiquinone-10-containing products with the methods disclosed in JP '394, as

the extraction process would function in the same manner as long as ubiquinone-10 is present in the starting material.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed August 13, 2007, have been fully considered but they are not persuasive. The applicant argues that steps [3], [4], and [5] of claim 1 produce a solution of ubiquionone-10 in methanol. However, it is respectfully noted that step [5] recites recovery of a "methanol solution containing ubiquinone-10" which does not signify that ubiquinone-10 is dissolved in methanol. Further still, the applicant argues that the instant invention involves the precipitation of ubiquinone-10 in step [2], but it is noted that step [2] does not recite that any sort of precipitation occurs, nor does the rest of claim 1 make any reference to precipitation. It is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim 1 requires recovering a "methanol solution containing ubiquinone-10." As pointed out above, the recitation of a "methanol solution containing ubiquinone-10" does not mean that ubiquinone-10 is dissolved in solution. Therefore, JP '394 still meets the limitations of the claims under examination.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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